

Experiment Number: 55312-01

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: Rat/F 344/N

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

Date Report Requested: 10/23/2014

Time Report Requested: 05:25:06

First Dose M/F: NA / NA

Lab: BAT

C Number: C55312B

Lock Date: 09/04/1992

Cage Range: All

Date Range: All

Reasons For Removal: All

Removal Date Range: All

Treatment Groups: All

Study Gender: Both

PWG Approval Date NONE

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P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]
 Test Compound: Coconut oil acid diethanolamine condensate
 CAS Number: 68603-42-9
 Date Report Requested: 10/23/2014
 Time Report Requested: 05:25:06
 First Dose M/F: NA / NA
 Lab: BAT

F 344/N Rat MALE	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG	400 MG/KG
Disposition Summary						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Survivors						
Terminal Sacrifice	10	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10
ALIMENTARY SYSTEM						
Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(0)	(10)
Liver	(10)	(0)	(0)	(0)	(0)	(10)
Hepatodiaphragmatic Nodule	1					1
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
CARDIOVASCULAR SYSTEM						
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Cardiomyopathy	6 [1.3]					4 [1.0]
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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Lab: BAT

F 344/N Rat MALE	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG	400 MG/KG
Parathyroid Gland	(6)	(0)	(0)	(0)	(0)	(7)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Epididymis	(10)	(0)	(0)	(0)	(0)	(10)
Preputial Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active	6 [1.3]					8 [1.8]
Prostate	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active	3 [1.3]					3 [1.7]
Seminal Vesicle	(10)	(0)	(0)	(0)	(0)	(10)
Testes	(10)	(0)	(0)	(1)	(0)	(10)
Germinal Epith, Degeneration				1 [2.0]		
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mandibular	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Spleen	(10)	(0)	(0)	(0)	(0)	(10)
Thymus	(10)	(0)	(0)	(0)	(0)	(10)
INTEGUMENTARY SYSTEM						
Mammary Gland	(8)	(0)	(0)	(0)	(0)	(9)
Skin	(10)	(10)	(10)	(10)	(10)	(10)
Epidermis, SOA, Hyperplasia		7 [1.1]		10 [1.4]	10 [2.3]	10 [2.9]
SOA, Inflammation, Chronic Active					8 [1.0]	10 [1.9]
SOA, Parakeratosis					3 [1.0]	9 [3.1]
SOA, Sebaceous Gl, Hyperplasia			6 [1.0]		9 [1.7]	10 [3.0]

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Lab: BAT

F 344/N Rat MALE	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG	400 MG/KG
SOA, Ulcer				1 [1.0]	6 [3.2]	7 [4.0]
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
RESPIRATORY SYSTEM						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Metaplasia, Osseous	1 [1.0]					
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Suppurative, Acute						1 [1.0]
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
Kidney	(10)	(9)	(9)	(9)	(5)	(10)
Renal Tubule, Regeneration	9 [1.0]	9 [1.2]	9 [1.1]	9 [1.1]	5 [1.0]	3 [1.0]
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

END OF MALE DATA

a - Number of animals examined microscopically at site and number of animals with lesion

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F 344/N Rat FEMALE	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG	400 MG/KG
Disposition Summary						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Survivors						
Terminal Sacrifice	10	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10
ALIMENTARY SYSTEM						
Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(0)	(10)
Liver	(10)	(1)	(1)	(1)	(2)	(10)
Artery, Dilatation					1 [4.0]	
Atrophy					1 [4.0]	
Hepatocyte, Hyperplasia					1 [4.0]	
Hepatodiaphragmatic Nodule	1	1	1	1	1	1
Inflammation, Chronic Active					1 [3.0]	
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Acinus, Atrophy	1 [1.0]					
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
CARDIOVASCULAR SYSTEM						
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Cardiomyopathy	1 [1.0]					

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ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(8)	(0)	(0)	(0)	(0)	(6)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Craniophar Dct, Pars Distalis, Cyst	2 [1.5]					
Pars Distalis, Cyst						1 [1.0]
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active	10 [1.0]					10 [1.0]
Ovary	(10)	(3)	(3)	(2)	(3)	(10)
Bilateral, Periovarn Tiss, Cyst					1 [2.0]	
Periovarn Tiss, Cyst	3 [1.3]	3 [2.0]	3 [2.0]	2 [2.0]	2 [2.0]	1 [2.0]
Uterus	(10)	(0)	(0)	(0)	(0)	(10)
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mandibular	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Spleen	(10)	(0)	(0)	(0)	(1)	(10)
Hyperplasia, Lymphoid					1 [2.0]	
Thymus	(10)	(0)	(0)	(0)	(0)	(10)
INTEGUMENTARY SYSTEM						
Mammary Gland	(10)	(0)	(0)	(0)	(0)	(10)

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Epidermis, SOA, Hyperplasia		2 [1.0]	10 [1.5]	10 [1.8]	10 [3.0]	10 [3.0]
SOA, Inflammation, Chronic Active				9 [1.0]	10 [2.8]	10 [3.0]
SOA, Parakeratosis					10 [3.4]	10 [4.0]
SOA, Sebaceous GI, Hyperplasia				7 [1.3]	10 [3.0]	10 [3.0]
SOA, Ulcer					10 [3.8]	10 [3.9]
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
RESPIRATORY SYSTEM						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Acute	1 [1.0]					
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Infarct					1 [4.0]	
Mineralization	10 [1.0]	10 [1.3]	10 [1.0]	10 [1.9]	10 [1.8]	10 [1.9]
Renal Tubule, Regeneration	3 [1.0]	5 [1.0]	7 [1.0]	10 [1.0]	10 [1.6]	10 [2.0]
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

** END OF REPORT **

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)